

Application No. 10/606,751  
Amdt. dated Apr-08-08  
Reply to Office Action of Jan-09-08

Amendments to the Claims:

1. (Original) A method for detecting the onset of inspiratory effort ( $T_{onset}$ ) in a patient on mechanical ventilation, comprising the steps of:
  - (a) monitoring airway pressure, rate of gas flow, and volume of gas flow of the patient;
  - (b) applying a gain factor ( $K_f$ ) to the signal representing rate of gas flow to convert the gas flow signal into a gas flow pressure signal;
  - (c) applying a gain factor ( $K_v$ ) to the signal representing volume of gas flow, also to convert the gas volume signal into a gas volume pressure signal;
  - (d) generating a composite pressure signal comprising the sum of airway pressure signal, gas flow pressure signal, and gas volume pressure signal, with all signals having suitably adjusted polarity;
  - (e) adjusting  $K_f$  and  $K_v$  to result in a desired linear trajectory of composite pressure signal baseline in the latter part of the exhalation phase;
  - (f) comparing (i) current composite pressure signal values with selected earlier composite pressure signal values, and/or
    - (ii) current composite pressure signal values with values expected at current time based on extrapolation of composite pressure signal trajectory at specified earlier times, and/or
    - (iii) the current rate of change in the composite pressure signal with a selected earlier rate of change in the composite pressure signal;
  - (g) comparing differences obtained from such comparison(s) made in step (f) with selected threshold values; and
  - (h) identifying  $T_{onset}$  when at least one of said differences exceeds said threshold values.
2. (Original) The method of claim 1 wherein the composite pressure signal incorporates a fourth component, consisting of the square of the rate of gas flow, to which a gain factor ( $K_{f2}$ ) is applied to convert said fourth signal to a pressure

Application No. 10/606,761  
Amdt. dated Apr-08-08  
Reply to Office Action of Jan-08-08

3

signal and where  $K_{f2}$  is also used to adjust the trajectory of composite pressure signal baseline in the latter part of the exhalation phase.

3. (Original) The method of claim 2 wherein  $K_{f2}$  is assigned a value corresponding to the  $K_2$  constant of the endotracheal tube in place in the patient.

4. (Original) The method of claim 1 wherein  $K_v$ ,  $K_f$  and/or  $K_{f2}$  are adjusted to result in a specified slope or pattern of composite pressure signal during part or all of the expiratory phase.

5. (Original) The method of claim 1 wherein a default value of  $K_f$  is used while the value of  $K_v$  is adjusted to obtain a desired baseline composite pressure signal trajectory.

6. (Original) The method of claim 1 wherein a default value of  $K_v$  is used while the value of  $K_f$  is adjusted to obtain a desired baseline composite pressure signal trajectory.

7. (Original) The method of claim 1 wherein the  $K_f$  value used is a known or estimated value of respiratory system resistance of the patient.

8. (Original) The method of claim 1 wherein the  $K_v$  value used is a known or estimated value of respiratory system elastance of the patient.

9. (Original) The method of claim 1 wherein current composite pressure signal value is compared with the composite pressure signal value at the most recent point where the composite pressure signal began a new rising phase and  $T_{onset}$  is identified when the calculated difference exceeds a set threshold value.

10. (Original) The method of claim 1 wherein  $T_{onset}$  detection is precluded in the early part of the exhalation phase.

11. (Original) The method of claim 1 wherein composite pressure signal amplitude is monitored through the inspiratory phase and wherein the end of

Application No. 10/606,751  
Amdt. dated Apr-08-08  
Reply to Office Action of Jan-09-08

4

inspiratory effort ( $T_{end}$ ) is identified from a reduction in composite pressure signal amplitude, or composite pressure signal slope, below a specified value.

12. (Original) The method of claim 11 wherein said specified value is a specified fraction of the highest value obtained earlier during said inspiratory phase.

13. (Original) The method of claim 11 wherein  $T_{end}$  detection is precluded in the early part of the inflation phase.

14. (Original) The method of claim 11 wherein signals corresponding to  $T_{end}$  are used to cycle off ventilator cycles.

15. (Original) A method for detecting the onset of inspiratory effort ( $T_{onset}$ ) in a patient on mechanical ventilation, comprising the steps of:

(a) monitoring airway pressure and rate of gas flow of the patient;

(b) applying a gain factor ( $K_f$ ) to the signal representing rate of gas flow to convert the gas flow signal into a gas flow pressure signal;

(c) generating a composite pressure signal comprising the sum of airway pressure signal and the gas flow pressure signal, with the two signals having suitably adjusted polarity;

(d) comparing (i) the current composite pressure signal values with values expected based on extrapolation of composite pressure signal trajectory at specified earlier times, and/or

(ii) the current rate of change of composite pressure signal with a selected earlier rate of change of composite pressure signal;

(e) comparing differences obtained from such comparison(s) made in step (d) with selected threshold values; and

(f) identifying  $T_{onset}$  when at least one of said differences exceeds said threshold values.

Application No. 10/606,751  
Amdt. dated Apr-08-08  
Reply to Office Action of Jan-09-08

5

16. (Original) The method of claim 15 wherein composite pressure signal incorporates a third component, consisting of the square of the rate of gas flow, to which a gain factor ( $K_{f2}$ ) is applied to convert said third signal to a pressure signal.
17. (Original) The method of claim 15 wherein selected  $K_f$  is known or assumed value of respiratory system resistance.
18. (Original) The method of claim 1 wherein generated signals representing  $T_{onset}$  are used to trigger ventilator cycles.
19. (Original) The method of claim 15 wherein generated signals representing  $T_{onset}$  are used to trigger ventilator cycles.
20. to 23. (Cancelled)
24. (Original) A device for detecting the onset of inspiratory effort ( $T_{onset}$ ) in a patient on mechanical ventilation, comprising:
  - circuitry for measuring airway pressure, rate of gas flow and volume of gas flow of the patient;
  - amplifier to apply a gain factor ( $K_f$ ) to the signal representing rate of gas flow to convert said signal into a gas flow pressure signal;
  - amplifier to apply a gain factor ( $K_v$ ) to the signal representing volume of gas flow to convert said signal into a gas volume pressure signal;
  - summing amplifier that generates a composite pressure signal comprising the sum of airway pressure signal, the gas flow pressure signal, and the gas volume pressure signal, with all signals having suitably adjusted polarity;
  - means to permit adjustment of  $K_f$  and  $K_v$  to provide a desired trajectory of composite pressure signal baseline in the latter part of the exhalation phase;

Application No. 10/606,751  
Amdt. dated Apr-08-08  
Reply to Office Action of Jan-09-08

## 6

circuitry to direct said composite pressure signal to a  $T_{onset}$  identification circuitry during a suitable period in the expiratory phase, said identification circuitry comprising circuitry to detect a change in trajectory; and means for generating a signal corresponding to  $T_{onset}$  when measured change in trajectory of composite pressure signal exceeds a specified threshold.

25. (Original) The device of claim 24 wherein an additional signal is generated to be summed by summing amplifier, said additional signal being generated by multiplying the flow signal by the absolute value of the flow signal and applying a gain factor ( $K_{f2}$ ) to the resulting squared flow signal using an amplifier and wherein  $K_{f2}$  is also used to adjust the trajectory of composite pressure signal baseline in the latter part of the exhalation phase.

26. (Original) The device of claim 25 wherein  $K_{f2}$  is assigned a value corresponding to the  $K_2$  constant of the endotracheal tube in place in the patient.

27. (Original) The device of claim 24 wherein  $K_f$  is fixed at a default value while adjustment of signal trajectory is made using  $K_v$  and/or  $K_{f2}$ .

28. (Original) The device of claim 24 wherein  $K_v$  is fixed at a default value while adjustment of signal trajectory is made using  $K_f$  and/or  $K_{f2}$ .

29. (Original) The device of claim 24 wherein the summing amplifier input related to the volume of gas flow is omitted.

30. (Original) The device of claim 24 including circuitry that precludes  $T_{onset}$  identification during a specified period after the end of ventilator's inflation phase.

31. (Original) The device of claim 24 wherein the  $T_{onset}$  identification circuitry comprises circuitry to obtain the rate of change in amplitude of the composite pressure signal and to obtain the difference between current said rate of change with said rate of change of the composite pressure signal at a specified earlier

Application No. 10/606,751  
Amtd. dated Apr-08-08  
Reply to Office Action of Jan-09-08

time, and to generate a  $T_{onset}$  signal when said difference exceeds a set threshold value.

32. (Original) The device of claim 24 wherein the  $T_{onset}$  identification circuitry comprises circuitry to measure the difference between current amplitude of the composite pressure signal and signal amplitude of the composite pressure signal at a specified earlier time, and to generate a  $T_{onset}$  signal when said difference exceeds a set threshold value.

33. (Original) The device of claim 24 wherein  $K_v$  and/or  $K_f$  and/or  $K_{f2}$  are adjusted to produce a horizontal or slightly downward sloping composite pressure signal baseline in the latter part of expiration and the  $T_{onset}$  identification circuitry comprises circuitry to measure the difference between current amplitude of the composite pressure signal and amplitude of the composite pressure signal at the most recent point where the composite pressure signal began rising, and to generate a  $T_{onset}$  signal when said difference exceeds a set threshold value.

34. (Original) The device of claim 24 wherein the generated composite pressure signal is gated to circuitry to identify end of inspiratory effort ( $T_{end}$ ) said circuitry comprising:

circuitry to identify the highest amplitude (peak) of the composite pressure signal reached during the current inspiratory effort;

circuitry to detect when amplitude of the composite pressure signal decreases below a specified value beyond the time at which said peak occurred; and

circuitry to generate a signal corresponding to  $T_{end}$  when said amplitude of the composite pressure signal decreases below said specified value.

35. (Original) The device of claim 34 where said specified value is a specified fraction of peak amplitude of the composite pressure signal.

36. (Original) The device of claim 34 wherein circuitry is provided to preclude detection of  $T_{end}$  during a specified period following ventilator triggering.

Application No. 10/606,751  
Amdt. dated Apr-08-08  
Reply to Office Action of Jan-09-08

37. The device of claim 24 wherein signals corresponding to  $T_{onset}$  are used to trigger ventilator cycles and/or signals corresponding to  $T_{end}$  are used to cycle off inflation phase of ventilator.
38. to 46. (Cancelled)